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10/780,394	02/17/2004	Stephen James Russell	07039-411002	1617

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EXAMINER

NGUYEN, QUANG

ART UNIT PAPER NUMBER

1633

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/780,394

Applicant(s)

RUSSELL ET AL.

Examiner

Quang Nguyen, Ph.D.

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 25-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09/043,665.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's amendment filed on 12/19/05 was entered.

Amended claim 25 and new claims 26-29 are pending in the present application, and they are examined on the merits herein.

### ***Claim Objections***

Amended claim 25 is still objected to because of the term "said nucleic acid encoding said polypeptide can be incorporate into the genome" is not grammatically correct. The phrase - - said nucleic acid encoding said polypeptide can be incorporated into the genome - - is more appropriate.

Claim 26 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 25. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). This is because both claims 25 and 26 are directed to the same retroviral packaging cell having the same components (e.g., a retroviral vector and an exogenous nucleic acid encoding a stem cell factor).

### ***Response to Amendment***

The rejection under 35 U.S.C. 112, first paragraph, was withdrawn in light of Applicant's amendment.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Paul et al. (WO 94/27643; IDS) as evidenced by Lyman et al. (Cell 75:1157-1167, 1993). ***This is a modified rejection necessitated by Applicant's amendment.***

Paul et al disclose the preparation of retroviral packaging cells producing retroviral vectors bearing chimeric targeting proteins (CTPs) on their surfaces for introducing a heterologous gene into targeted cells, wherein chimeric targeting proteins comprised a ligand moiety that is a cytokine exhibiting cytokine effector activity to be used to modulate the growth, differentiation or other activity of the targeted cells (see Summary of the invention, particularly, page 6, lines 1-30). Paul et al further disclose that cytokines to be used in their invention include interleukins (IL1-13), GM-CSF, G-CSF, M-CSF, EPO, LIF, interferons, chemotactic factors, growth factors such as EGF, FGFs, PDGFs and others known in the art, including the cytokine that interacts with the flk-2 receptor on totipotent hematopoietic stem cells (page 14, lines 1-28). At the effective filing date of the present application, the cytokine that interacts with the flk-2 receptor is Flt3 ligand or stem cell factor as evidenced by the teachings of Lyman et al. (see at least abstract). Paul et al specifically teach that a chimeric targeting protein generally comprises a signal peptide for insertion through the

plasma membrane and is expressed in a packaging cell line such as LGPS (page 8, lines 10-22), and that cytokines may be either secreted from the cells that synthesize them or they may be membrane-bound such as MGF and CSF (page 21, lines 18-21).

Therefore, the cytokine having growth modulating activity will be displayed on the surface of the retroviral packaging cells. Paul et al also teach that the CTP contains a flexible peptide linker sequence separating the ligand moiety and the uptake moiety to enhance the ability of the moieties to adopt conformations relatively independently of each other (at least page 8, lines 6-9). Paul et al teach that the majority of the amino acids making up the flexon will preferably be amino acids having small side chains such as glycine, alanine, valine, leucine, isoleucine and serine, and the flexon comprise about four and one hundred amino acids (page 30, lines 3-17). Since the flexon is made up of amino acid residues, it is cleavable by a protease. Paul et al further exemplified a DNA sequence encoding IL-2 fused upstream and in frame with a sequence encoding the envelope protein of the ecotropic MoMLV or the amphotropic murine virus 4070A (see at least Fig. 2 and Fig. 4), and it is noted that the viral envelope protein contains an external, glycosylated polypeptide named "SU" protein (page 12, lines 25-31). Additionally, Paul et al teach that the sequence encoding the CTP can be stably integrated into the genome of the packaging cell line or may be present on an extrachromosomal element such as a plasmid or other factor (page 33, lines 27-29), and a heterologous gene to be introduced into targeted cells include both positive and negative selectable genes (neo, HSV-I TK, HPRT, APRET) as well as numerous other foreign genes (page 36, line 5 continues to line 6 of page 37).

Accordingly, the retroviral packing cells of Paul et al meet all the limitation of the instant claims, and therefore the instant claims are anticipated by the reference. It should be noted that for a composition claim, its intended use is not given any patentably weight in light of the prior art. Furthermore, please, also note that where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke*. Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

### ***Response to Arguments***

Applicant's arguments related to the above rejection in the Amendment filed on 12/19/05 (page 5) have been fully considered, but they are respectfully not found persuasive.

Applicants argue basically that the Paul et al. reference does not disclose a retroviral packaging cell comprising an exogenous nucleic acid encoding a stem cell factor, and that Applicants unexpectedly found that it is possible to incorporate nucleic

acid into quiescent cells such as hematopoietic stem cells by using the presently claimed retroviral packaging cells, which display the stem cell factor on their surface.

Please note that Paul et al clearly teach the preparation of retroviral packaging cells producing retroviral vectors bearing chimeric targeting proteins (CTPs) on their surfaces for introducing a heterologous gene into targeted cells, wherein chimeric targeting proteins comprised a ligand moiety that is a cytokine exhibiting cytokine effector activity to be used to modulate the growth, differentiation or other activity of the targeted cells, and that the cytokine includes one that interacts with the flk-2 receptor on totipotent hematopoietic stem cells (page 14, lines 1-28). At the effective filing date of the present application, the cytokine that interacts with the flk-2 receptor is Flt3 ligand or stem cell factor as evidenced by the teachings of Lyman et al. (see at least abstract). Additionally, Paul et al teach that the sequence encoding the CTP can be stably integrated into the genome of the packaging cell line or may be present on an extrachromosomal element such as a plasmid or other factor (page 33, lines 27-29), and a heterologous gene to be introduced into targeted cells include both positive and negative selectable genes (neo, HSV-I TK, HPRT, APRET) as well as numerous other foreign genes (page 36, line 5 continues to line 6 of page 37). Thus, the retroviral packing cells of Paul et al meet all the limitation of the instant claims, and therefore the instant claims are anticipated by the reference.

The instant claims are drawn to an isolated retroviral packaging cell having the recited limitation, and not a method of incorporating nucleic acid into quiescent cells by

the retroviral packaging cell in which Applicants claim to find an unexpectedly result. Furthermore, the above rejection is under 35 U.S.C. 102(b).

### ***Conclusion***

#### ***No claim is allowed.***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, Celine Qian, Ph.D., may be reached at (571) 272-0777, or SPE, Dave Nguyen, at (571) 272-0731.

**To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.**

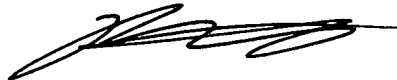


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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*Quang Nguyen, Ph.D.*

CELINE QIAN, PH.D.  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'C. Qian', written in a cursive style.